



## METHODS AND DEVICES FOR TISSUE RECONFIGURATION

### Field of the Invention

This invention relates generally to endoscopic methods and devices for reconfiguring  
5 tissue within a hollow body organ and more particularly to such methods and apparatus used  
to reduce the reflux of contents of one hollow organ into another hollow organ.

### Background of the Invention

Gastroesophageal reflux disease (GERD) is a common upper-gastrointestinal disorder  
10 with a prevalence of approximately 5 percent in the Western world. GERD is a condition in  
which acidic contents of the stomach flow inappropriately from the stomach into the  
esophagus. GERD causes heartburn when accompanied by irritation of the esophagus.  
Chronic irritation of the esophagus leads to inflammation of the esophagus, known as  
esophagitis. In addition to esophagitis, complications of GERD include Barrett's esophagus,  
15 esophageal stricture, intractable vomiting, asthma, chronic bronchitis, and aspiration  
pneumonia. Approximately 25 percent of individuals with GERD fail pharmacological  
therapy and become candidates for a surgical anti-reflux procedure. The estimated total direct  
and indirect costs of GERD treatment in the United States are in excess of 100 billion dollars  
annually.

20 The focus of attention in understanding the pathophysiology of GERD has for many  
years been the lower esophageal sphincter (LES), thought to be a ring of smooth muscle  
located at the gastroesophageal junction (GEJ) near where the lower esophagus communicates  
with the entrance to the stomach. Normally the LES allows food to pass from the esophagus  
to the stomach, while otherwise remaining closed, thus preventing reflux. Closure of the LES  
25 is an active process, requiring a combination of proper mechanics and intact innervation.  
Additionally, the diaphragm may act on the esophagus normally to keep it closed at the LES.

Backflow of gastric contents into the esophagus results when gastric pressure is  
sufficient to overcome the pressure gradient that normally exists at the GEJ or when gravity  
acting on the contents is sufficient to cause flow through the GEJ. This situation arises when  
30 the gastric pressure is elevated or when the competence of the LES is compromised. Gastric  
pressure is elevated in association with eating, bending at the waist or squatting, constriction  
of the waist by clothing, obesity, pregnancy, partial or complete bowel obstruction, etc.